

Application Serial No. 10/774,803
Filed February 9, 2004
Response dated March 16, 2007
Reply to Office Action dated February 26, 2007
Attorney Docket No. XANO-42

RESPONSE TO RESTRICTION REQUIREMENT

This paper is responsive to the Office Action mailed on February 26, 2007, requiring restriction to one set of claims to pursue in the above-identified application.

The Examiner stated in the Office Action that this application contains claims directed to the following patentably distinct inventions: Group I, including claims 1 and 20, drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA and monothioglycerol (MTG) or glutathione; Group II, including claims 21-41, and 62, drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA, monothioglycerol or glutathione, and ascorbic acid; Group III, including claims 42-61, drawn to a formulation comprising a therapeutically effective amount of levomepromazine, EDTA, ethylgallate or cysteine, and ascorbic acid; Group IV, including claim 63, drawn to a formulation comprising a therapeutically effective amount of levomepromazine HCl, ascorbic acid, EDTA, and MTG; Group V, including claims 64-65, drawn to a stable terminally sterilized formulation comprising a therapeutically effective amount of levomepromazine wherein said formulation contains a concentration of total impurities of less than about 3% by weight per volume of the formulation and is terminally sterilized; Group VI, including claims 66-73, drawn to a method of stabilizing a formulation of levomepromazine, comprising levomepromazine, EDTA, MTG or glutathione, and sparging said formulation with an oxygen-free inert gas; Group VII, including claims 74-82, drawn to a

method for stabilizing a formulation of levomepromazine comprising a therapeutically effective amount of levomepromazine, EDTA, MTG, and ascorbic acid; Group VIII, including claims 83-90, drawn to a method for stabilizing a formulation of levomepromazine comprising levomepromazine, EDTA, ethylgallate or cysteine, and ascorbic acid, and sparging said formulation with an oxygen-free inert gas; Group IX, including claims 1 and 91, drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine, EDTA, and monothioglycerol (MTG) or glutathione; Group X, including claims 21 and 92, drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine, EDTA, monothioglycerol or glutathione, and ascorbic acid; and Group XI, including claims 42 and 93, drawn to a method of treating a disorder in a patient in need thereof, comprising administering a formulation a therapeutically effective amount of levomepromazine, EDTA, ethylgallate or cysteine, and ascorbic acid.

In response, Applicant hereby elects the claims of Group V without traverse. Group V includes claims 64-65, drawn to a stable terminally sterilized formulation comprising a therapeutically effective amount of levomepromazine wherein said formulation contains a concentration of total impurities of less than about 3% by weight per volume of the formulation and is terminally sterilized.

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Conclusion

No fee is believed due. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000. The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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